UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/724,575 | 11/28/2000 | Dale B. Schenk | 15270J-005912US | 6096 |

7590 11/21/2002

Nina M. Ashton
Elan Pharmaceuticals, Inc.
800 Gateway Boulevard
South San Francisco, CA 94080

| EXAMINER |
|---|
| NICHOLS, CHRISTOPHER J |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 11/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/724,575 | SCHENK, DALE B. | |
| | Examiner | Art Unit | |
| | Christopher Nichols, Ph.D. | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 26-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

| NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES | Application No. 09/724,575 | Applicant(s) SCHENK, DALE B. | |
|---|---|---|---|
| | Examiner Christopher Nichols, Ph.D. | Art Unit 1647 | |

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐7. Other: See attached form.

Applicant Must Provide:

☒ An initial computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

November 18th, 2002
CJN

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group II (claims 11-25) as claim 13 reads on transthyretin and claim 15 reads on ATTR in Paper No.9 (26 September 2002) is acknowledged. The traversal is on the ground(s) that there is nothing in the Examiner's Election/Restriction requirement (Paper No. 7) to excuse a refusal to examine an elected invention or a generic claim reading thereon. This is not found persuasive because the precursor proteins listed in claim 13 and their respective fragments listed in claim 15 are not members of a Markush group. Each protein/fragment pair belongs to independent and distinct diseases and disorders. Each would require an independent, non—overlapping, and distinct search; therefore the restriction requirement is maintained. Claims 1-10 and 26-57 from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected material, there being no allowable generic or linking claim. Claims 11-25 will be examined to the extent that they read on a method of preventing or treating a disorder characterized by amyloid deposition in a mammalian subject, comprising administering to a subject a dosage of transthyretin or ATTR effective to produce an immune response against an amyloid component characteristic of said disorder.

### *Status of Application, Amendments, and/or Claims*

2. Claims 1-10 and 26-57 are withdrawn from consideration, as discussed above, and claims 11-25 are under examination.

3. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

***Information Disclosure Statement***

4. The information disclosure statement filed 11 December 2001 (Paper No. 6) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because citations #144, #162, #174, and # 186 do not have dates listed, citation #187 was not present in the information disclosure statements. It has been placed in the application file, but the citation(s) listed above have not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

***Specification***

5. The specification is objected to because of the following informalities: "E. coli", "Shigella", and "Salmonella" are generally italicized (throughout document); the first line of the specification must state the parent application number to which it claims priority as a continuation; the specification is missing pp. 96. The resulting gap must be corrected. However, the entry of new matter is not permitted. Support for all entry of new material to the specification must be supported as originally filed material (e.g. reference to specific pages of the priority

document). Please delete the phrase "[REMAINDER PAGE INTENTIONALLY BLANK]" (pp. 88, 98, and 100). Appropriate correction is required.

***Sequence Rules***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. This application discloses an amino acid sequence on pp. 25, 44, 46, 47, and 75. Correction is required see "Notice to Comply" attached.

***Drawings***

7. The drawings are objected to because: Figure 11 does not contain a legend to define the symbols used; the brief description in the disclosure for Figure 15 does not contain a description of each part (A-E); the figure title for Figure 16 is mislabeled as "AB" and not "A-beta" or "Aβ". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

8. Claims 11-25 are objected to because of the following informalities: specifically recite non-elected material. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 11-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10. Claim 11 is directed to a method of preventing or treating a disorder characterized by amyloid deposition in a mammalian subject, comprising administration to the subject of a dosage of an agent effective to produce an immune response against an amyloid component characteristic of said disorder. Claim 12 is directed to the method of claim 11 wherein said amyloid component is a fibril protein or peptide. Claim 13 is directed to the method of claim 12 wherein the precursor protein is transthyretin. Claim 14 is directed to the method according to claim 13 wherein said agent induces an immune response directed against a neoepitope formed by said amyloid component with response to said precursor protein. Claim 15 is directed to the method of claim 13 wherein said amyloid component is ATTR. Claim 16 is directed to the method of claim 15 wherein said agents are described. Claim 17 is directed to the method of

claim 11 where said agent is effective to induce an immunogenic response against at least two different amyloid components. Claim 18 is directed to the method of claim 17 wherein said administering includes administering at least two amyloid fibril components. Claim 19 is directed to the method of claim 11 where said agent is a peptide linked to a carrier protein. Claim 20 is directed to any of the claims 11-19 wherein said administering further includes an adjuvant. Claim 21 is directed to the method of claim 20 wherein said adjuvant is QS21, monophosphoryl lipid, alum, or Freund's adjuvant. Claim 22 is directed to the method of claim 11 wherein said immunological response is characterized by a serum titer of at least 1:1000 with respect to said amyloid component. Claim 23 is directed to the method of claim 22 where in said serum titer is at least 1:5000 with respect to said fibril component. Claim 24 is directed to the method of claim 11 wherein said immunological response is characterized by a serum amount of immunoreactivity corresponding to a greater than four times higher than a serum level of immunoreactivity measured in a pre-treatment control serum sample. Claim 25 is directed to the method of claim 24 wherein said serum amount of immunoreactivity is measured at a serum dilution of about 1:100.

11. The specification teaches that the administration of particular $A\beta_{42}$ (AN1792) fragments in with an immunogenic adjuvant is able to reduce β-amyloid levels within the brains of mice which are transgenic for PDAPP. These mice exhibit Alzheimer type over production and build up of β -amyloid within the brain. However, as recognized in the art, these mice do not exhibit Alzheimer's disease as in humans or plaque morphology and components which are the same as in humans, Alzheimer's disease, Down's Syndrome or other amyloidogenic diseases, see in

particular Schenk et al., Nature, 400:173-77, 1999, Games et al., Nature 373(6514): 523-7, 1995 and Chen et al., Progress in Br. Res., 117:327-34, 1998.

12. However, administration of $A\beta_{42}$ to Alzheimer's patients is not predictive of how administration of transthyretin and/or ATTR affects patients with amyloid-related diseases or any given amyloid dependent disorders. There are no working examples directed to transthyretin or ATTR or diseases caused by transthyretin or ATTR.

13. Furthermore, the method is based upon findings which show particular strategies of targeting plaque removal via antigen or antibody administration. Evidence that such therapy can be effective in the removal of amyloid plaque burden is exhibited by Lemere et al., Society for Neuroscience Abstracts, vol. 25, part I, Abstract 519.6, 29th Annual Meeting 10/23-10/28, 1999, and Schenk, Nature, 400:173-177, (1999) using antigen and DeMattos, PNAS 98(15): 8850-8855, 2001 using antibody administration (Raso, V.A., Immunotherapy Weekly, Abstract "Immunotherapy of Alzheimer's Disease", (1998).

14. Thus the claimed invention is directed using ATTR to produce an immune response against an amyloid component characteristic of an amyloid disorder, which is not supported by the teachings of the specification or the prior art (Tennent et al., 1995; Stein and Johnson, 2002). One skilled in this art would be expected to reasonably doubt that the claimed method would work due to the following obstacles: Specific biological actions/activities that the antigenic composition of ATTR and an adjuvant would effect; How does the immunogenic effect on amyloid deposition relate to symptoms of any given amyloid disorder; Expectation of that ATTR would be actively involved in amyloid deposition, as opposed to being a non-dynamic component (USPT 5851996; USPT 5780587; Perutz et al., 2002). The specification does not

provide guidance on how to overcome expected obstacles. The scope of patent protection sought by Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure provided by the specification and prior art for the following reasons.

15. Regarding immune response, the art recognizes that immune responses include two large branches, humoral and cellular. Due to the large quantity of experimentation necessary to evaluate all the possible aspects of both humoral and cellular immune responses, the lack of direction/guidance presented in the specification which aspects of the immune response are most relevant, the absence of working examples directed to all aspects of immune responses, the complex nature of the invention, the unpredictability of the effects of antigens on the mammalian immune system (Chapman, 2000; Frenkel et al., 1999; Frenkel et al., 1998; Frenkel et al., 2000; Friedland et al., 1997), and the breadth of the claims which fail to recite limitations for which aspects of a mammalian immune response are activated, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

16. Regarding the ancillary effects of the introduction of an immune response in a mammalian nervous system, the specification must establish that the antigens injection into the subjects produce a specific immune response and do not act as pyrogens (leading to cranial swelling for example). Due to the large quantity of experimentation necessary to evaluate all the effects of the difficulty of predicating an immune response in the nervous system, the lack of direction/guidance presented in the specification about collateral damage due to a vigorous immune response in an immunological privileged area (such as the nervous system), the absence of working examples directed to successful antigen presentation of a neurological protein, the complex nature of the invention, the unpredictability of the effects of antigens on the mammalian

nervous system, and the breadth of the claims which fail to recite limitations for what constitutes a successful, controlled immune response in the mammalian brain, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope (Elan press releases; Grubeck-Loebenstein et al., 2000; USPN 598883).

17. Regarding, mutants, fragments, and peptides, the skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition see in particular Skolnick et al. (2000). For example, Jobling et al. (1991) teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of conserved structural components to both biological function and immunological recognition. The skilled artisan also recognizes that immunological responses depend upon the structural characteristics (conformation) of the particular protein (amino acid sequence) targeted.

18. For instance, Tanaka et al. (1998) demonstrates that administration of β-amyloid (1-40) into the cerebral ventricle of rats produces learning and memory deficits accompanied by dysfunction in the cholingergic and dopaminergic systems (Abstract). Therefore, instead of eliciting a salubrious immune response to alleviate a β-amyloid disorder, such as Alzheimer's disease, the administration of the β-amyloid protein or fragments thereof can lead to detrimental neurological effects.

19. Finally, the application must establish a nexus between the specific immune response recited in the claims for each amyloid related disorder and the alleviation of said disease state

recited in the claims. In this case, the skilled artisan is not guided as to how an immune response must affect one or more activates of each targeted fibril protein or peptide such that the immune response would be determined to be one that alleviates said disorder. Also, amyloid related disorders are varied and it is not clear that these fibril protein or peptides would be sufficiently involved in a rate-limiting step for any amyloid related disorder such that it could be used in a to elicit a specific and sufficient immune response to slow or prevent the deposition plaque material thereby providing relief from said disorder (Small et al., 2001; Chapman, 2000; Esiri, 2001; St. George-Hyslop and Westaway, 1999; Younkin, 2001; Tennent et al., 1995; Stein and Johnson, 2002).

***Claim Rejections - 35 USC § 101***

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

20. Claims 11-25 of this application conflict with claims 11-25 of Application No.'s 09/585817, 09/724567, 09/724570, 09/979952, and 09/724953. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims,

elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

22. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

23. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 11-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 10-15, 18-19, 21, 26-27, 32-40, 68-69, 71-74, and 81 of Application **09/201430**, claims 44-45, 48, and 67-88 of Application **09/723927**, 67-101 of Application **09/724489**, claims 38, 40, 42-52, and 56-59 of Application **09/723760**, claims

31-58 of Application **09/724940**, claims of 1-2, 7, 10-11, and 14-25 of Applications **09/724921** and **09/724929** claims 48-84 of Application **09/979701**, claims 79-81 of Application **09/723544**, claims 1-6, 8-9, and 11-28 of Applications **09/723765** and **09/724291**, claims 1-2, 7, 17, 20, and 26-31 of Application of **09/204838**, claims 39-42 of Application **09/723725**, claims 90-97 of Application **09/980568**, and claim 27 of Application **09/579690** in view of Jen et al. (1997) and USPN 5780587 taken with WO 99/06545. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of **09/201430, 09/723927, 09/724489, 09/723760, 09/724940, 09/724921, 09/724929, 09/979701, 09/723544, 09/723765, 09/724291, 09/204838, 09/723725, 09/980568**, and **09/579690** describe administering an Aβ peptide to a subject, including but not limited to mammals such as humans, in a regime effective to induce an immune response to a Aβ peptide, fragment, or synthetic equivalent and thereby prevent or treat the amyloid disease, including but not limited to Alzheimer's disease thus meeting the limitations of claims 11-25 of the instant Application 09/585817.

25. Regarding eliciting an immune response, the art recognizes that immune response includes humoral, or B-cell mediated antibody production, and cellular, or T-cell mediated phagocytosis. Both B-cells and T-cells produce cytokines that activate and recruit more immune cells in a positive feedback loop to augment the immune response thus meeting the limitations of Claim 11 (see discussion above).

26. Regarding Alzheimer's disease reading on fibril components derived form a precursor protein in the instant application, amyloid β protein precursor (β-APP) is a key protein the development of Alzheimer's disease thus meeting the limitations of Claims 11-18 (USPN 5780587).

27. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a fragment of Aβ because amyloid β protein precursor (β-APP) and fragments thereof are immunogenic (Jen et al., 1997).

28. The person of ordinary skill in the art would have been motivated to make those modifications because several neurodegenerative diseases, including but not limited to Alzheimer's disease, have the motif insoluble deposits of protein, known as plaques, aggregates, or fibrils, that are held to be key to the cause of the particular malady. The inhibition or elimination of said insoluble deposits of proteins at the time of the invention was seen as a desirable method by which said malady could be prevented, treated, or a way to alleviate symptoms (WO 99/06545; USPN 5780587).

***Summary***

29. Claims 11-25 are hereby rejected.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher J. Nichols whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kunnum

CJN
November 15, 2002